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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,513	11/18/2005	Roy R. Lobb	BII-00101	2848

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,513	LOBB, ROY R.	
	Examiner	Art Unit	
	JEGATHEESAN SEHARASEYON	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *105,106,108-111,113,114,119 and 133* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-72, 74-77, 79, 80, 85, 99 and 139-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 70-72,74-77,79,80,85,99,105,106,108-111,113,114,119,133 and 139-148.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/2009 has been entered. An action on the RCE follows.

2. Claims 70-72, 74-77, 79, 80, 85, 99, 105, 106, 108-111, 113, 114, 119, 133 and 139-148 are pending. Claims 105, 106, 108-111, 113-114, 119 and 133 remain withdrawn. Claim 70 is amended. Therefore claims 70-72, 74-77, 79, 80, 85, 99 and 139-148 are pending and examined.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Claim Objections

4. Claims 140, 141 and 142 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 70 on which these claim depend already states that the condition is not due a virus.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70-72, 74-77, 79, 80, 85, 99 and 139-148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 70 is rejected as vague and indefinite for reciting that the indication for treatment is selected from the group consisting of lupus or viral disease. Lupus is a species and viral disease is genus. The specification has failed to define the term so as to set forth the meets and bounds of the invention (The specification recites viral disease to be hepatitis infection in page 42). Claims 71, 72, 74-77, 79, 80, 85, 99 and 139-148 are rejected insofar as they are dependent on rejected claim 70.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6a, The rejection of claims 70-72, 74-77, 79, 80, 85, 99 and 139-148 under 35 U.S.C. 103(a) as being unpatentable over Schwarting et al. (2001, PTO 1449 of 6/2/06) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) and Chang et al. (U. S Patent No. 5, 908, 626) is maintained for reasons set forth in the Office Action dated 12/24/2008 (pages: 8-9).

Applicant argues that Schwarting et al (2001) teaches the treatment of an underlying lupus disease. Applicant is submitting that that at the time of filing there existed no reasonable expectation of success that a method for treating glomerulonephritis in a mammal who is otherwise free of indications for treatment with IFN-β, said indications selected from the group consisting of lupus or viral disease, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic, would be effective absent the teachings of the present specification. It is further argued that based on the teachings of Schwarting et al. in view of Pedersen et al. and Chang et al., one skilled in the art would have no reasonable expectation of success that IFN-β treatment of glomerulonephritis would be effective absent amelioration of an underlying lupus disease. It is also asserted that Schwarting et al. in view of Pedersen et al. and Chang et al. does not teach a method for treating glomerulonephritis in a mammal consisting essentially of identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic, as recited in claims 143, 144 and 148. Applicant asserts that the subject matter of claims 143, 144 and 148 is such that identifying a mammal having lupus is not required. Applicant is also

claiming that Schwarting et al. reference teaches away from the methods of the Applicant's claims. Specifically, Applicant asserts that the reference teaches away from treating glomerulonephritis in a mammal who is otherwise free of indications (lupus or viral disease) for treatment with IFN-β. Applicant's arguments have been fully considered but are not found to be persuasive.

Contrary to Applicant's assertion, there is a reasonable expectation of success of treating glomerulonephritis in a mammal by administering IFN-β because the Schwarting et al. reference teaches that MRL-*Fas*^{lpr} mice treated with IFN-β show improvement in nephritis. Further, the reference teaches that IFN-β is useful in the treatment of patients with multiple sclerosis (an auto immune disease). As evidenced by JAX Mice database (included) MRL-*Fas*^{lpr} mice show systemic autoimmunity, massive lymphadenopathy associated with proliferation of aberrant T cells, arthritis, and immune complex glomerulonephritis. Therefore absent evidence to the contrary treating the autoimmune condition with IFN-β will treat glomerulonephritis and improve renal function. Thus, the rejection of claims 70-72, 74-77, 79, 80, 85, 99 and 139-148 under 35 U.S.C. 103(a) as being unpatentable over Schwarting et al. (2001, PTO 1449 of 6/2/06) in view of Pedersen et al. (U. S Patent No. 6, 531, 122) and Chang et al. (U. S Patent No. 5, 908, 626) is maintained.

Conclusion

7. No Claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEGATHEESAN SEHARASEYON whose telephone number is (571)272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
6/4/09
/Jegatheesan Seharaseyon/
Examiner, Art Unit 1647